THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700
Philadelphia, PA 19103-7077
215.575.9050 Phone
215.575.4939 Fax

901 E Street NW, 10th Floor
Washington, DC 20004
202.552.2000 Phone
202.552.2299 Fax
www.pewtrusts.org

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Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-P
Room 5527, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: OIG-0936-P Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Inspector General Levinson:

The Pew Charitable Trusts (Pew) is pleased to offer comments on the Proposed Rule titled Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees ("the proposed rule").[1] Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need.

Pew commends the Department of Health and Human Services (HHS) for its commitment to addressing drug spending in the Medicare Part D and Medicaid programs. While we share HHS' concern with the high out-of-pocket costs paid by Medicare beneficiaries, we are concerned about the increased costs associated with the proposed rule compared with the limited savings beneficiaries would receive. As Medicare's own estimates (discussed in more detail below) project, the proposed rule will increase seniors' Medicare Part D premiums by 25 percent, increase Medicare spending by $196 billion, and increase drug manufacturer revenues by $171 billion. The net effect will be higher taxpayer spending on prescription drugs.

[1] 84 Federal Register 2340-2363. Department of Health and Human Services, Office of Inspector General. OIG-0936-P; Fraud and Abuse; Remove of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (RIN 0936-AA08). February 6, 2019.

This letter outlines the impact of the proposal on drug prices, on Medicare and Medicaid spending, on manufacturer revenues, and on beneficiary spending. We also compare the fiscal impact of this proposal to other recent Congressional proposals addressing drug spending, and we outline alternative strategies to reduce seniors' pharmacy payments. Throughout this letter, we refer to financial modeling performed by the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT).[2] As part of the proposal, HHS commissioned three separate financial models. The first two models (including the CMS OACT model), dated August 30, 2018, showed significant increases in Medicare spending under the proposal.[3] The third analysis, dated January 31, 2019, included a range of estimates that generated both increased Medicare spending and Medicare savings.[4] However, the estimates of Medicare savings presume that either Medicare Part D plans will increase drug access restrictions or that drug manufacturers will offer greater discounts, two scenarios that may be less plausible. Therefore, this letter relies on the initial CMS OACT estimate.

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Overview of the Proposal

Currently, Medicare Part D plans negotiate discounts with pharmaceutical manufacturers for favorable treatment of a manufacturer's drugs. These negotiations are typically administered by a Pharmacy Benefits Manager (PBM), and these discounts take the form of a periodic rebate payment from the manufacturer to the PBM based on the quantity of drugs used by each plan's beneficiaries.[5] Because these rebates are paid after a beneficiary has already purchased and used a particular drug, these payments generally do not affect a beneficiary's pharmacy payments; instead, PBMs and plans use these payments to offset total spending, reducing premium costs for all beneficiaries.[6] Under the proposal, drug manufacturers would be required to offer the discount when the beneficiary purchases the drug. If the beneficiary's pharmacy payment is calculated as a percentage of the drug's cost (called "co-insurance"), this discounted pharmacy price would result in a lower pharmacy payment by the beneficiary compared with the current system.[7] To achieve this policy change, the proposal changes an exception to the Anti-Kickback Statute that allows manufacturers to offer discounts via rebate payments. Under the proposal, rebates would now be considered illegal kickbacks, but pharmacy discounts would be protected.[8]

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[2] Centers for Medicare & Medicaid Services, Office of the Actuary (CMS OACT). "Proposed Safe Harbor Regulation." August 30, 2018.
[3] Wakely Consulting Group. "Estimate of the Impact of Eliminating Rebates for Reduced List Prices at Point-of Sale on Beneficiaries." August 30, 2018.
[4] Milliman. "Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates." January 31, 2019. Note that the proposal dates the Milliman analysis to September 2018 in its citations, but the version released with the proposal is dated January 31, 2019.
[5] Pharmaceutical Care Management Association. "Our Industry: What is a PBM?" https://www.pcmanet.org/our-industry.
[6] 84 Fed. Reg. 2341.
[7] 84 Fed. Reg. 2353.
[8] 84 Fed. Reg. 2348-2350.

Impact on Drug Prices

The proposal is unlikely to reduce drug prices; indeed, it is more likely to increase drug prices. The CMS OACT model estimates that manufacturers will reduce their total discounts by 15 percent when switching from a rebate to a pharmacy discount;[9] based on CMS OACT's estimated current 24 percent rebate,[10] this correlates to a 5 percent increase in net drug prices for the Medicare Part D program.[11]

In addition, the proposal could lead to a circumstance that the Federal Trade Commission (FTC) has identified as a risk for anticompetitive behavior by manufacturers that would increase prices. Currently, manufacturer rebates to PBMs are secret, and two competing manufacturers do not know the rebate offered by their competitor. However, the proposal acknowledges that entities could "reverse engineer" the discounts provided.[12] The FTC warns that this type of price transparency may "allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price or increases the likelihood that they can coordinate on higher prices."[13] Empirical evidence from outside the drug industry lends support for this theory: In the early 1990's, the Danish Competition Council required the publication of privately negotiated discounts for ready-mixed concrete; following this publication, prices rose 15-20% within a year, which experts attribute to increased collusion among the oligopoly of producers.[14] In the brand drug market, where a limited number of manufacturers offer similar products within a therapeutic class, net price transparency may cause these manufacturers to collectively raise prices.

Impact on Medicare Spending

The CMS OACT estimates the proposal will increase Medicare spending by $196.1 billion over ten years.[15] This increased spending has two drivers: 1) the higher net cost of drugs under the proposal, and 2) the structure of the Medicare Part D program. The higher net cost of drugs, discussed in the previous section, accounts for a significant portion of the increased Medicare spend, but the structure of the Medicare Part D program drives a $39.8 billion increase.

Medicare Part D is financed by three parties: beneficiaries, the Medicare program (through taxpayers), and manufacturers. Beneficiaries and the Medicare program make premium payments that plans use to pay for a portion of pharmaceutical costs, with the remainder paid by beneficiary cost-sharing payments at the pharmacy counter. However, once the plan and the beneficiary together have paid at least $3,820 to the pharmacy, the "coverage gap" phase of the Medicare program begins, and manufacturers are

[9] CMS OACT. "Proposed Safe Harbor Regulation," p.3. August 30, 2018.
[10] CMS OACT. "Proposed Safe Harbor Regulation," p.4. August 30, 2018.
[11] Under the proposal, the net price on a $100 drug would be $100 - .85*$24, or $79.60, a 4.7 percent increase over the current estimated price of $76 ($100-$24).
[12] 84 Fed. Reg. 2349.
[13] Koslov, TI, Jex, E. "Price transparency or TMI?," Federal Trade Commission, July 2, 2015, https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.
[14] Albæk, Svend, Peter Møllgaard, and Per B. Overgaard. "Government-assisted oligopoly coordination? A concrete case." The Journal of Industrial Economics 45.4 (1997): 429-443.
[15] CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.

required to offer a discount to offset costs.[16] This manufacturer discount, called the coverage gap discount, increased from 50 percent to 70 percent of drug costs in 2019 following changes Congress made in 2018.[17] Currently, manufacturer rebates do not affect the calculation of the $3,820 threshold.

Under the proposal, discounts applied at the pharmacy counter would slow the accumulation of $3,820 in pharmacy payments, reducing the number of beneficiaries that reach the coverage gap phase. That means fewer beneficiaries will be eligible for manufacturer coverage gap discounts, reducing manufacturers' contributions to the Medicare Part D program. CMS OACT estimates that this change will reduce manufacturers' coverage gap payments by $39.8 billion over ten years[18] – payments that will now be covered through increased Medicare and beneficiary premiums.

Impact on Manufacturer Revenue

Based on CMS OACT estimates, manufacturer revenue would increase by approximately $171 billion over ten years under the proposal. This increased revenue is driven by both the reduction in total discounts offered under the program as well as the reduction in manufacturer contributions in the coverage gap, discussed above. While total Medicare spending will increase by $196.1 billion, net beneficiary spending will decrease by $25.2 billion (discussed below), resulting in a net increase in drug payments of $170.9 billion.[19] While it is possible that some of these increased payments will be retained by pharmacies, Medicare plans, or PBMs, because these increased payments are driven by higher prices and lower coverage gap contributions, manufacturers will receive nearly all of this increased spending as revenue.

Manufacturers would also see greater revenue from reduced rebates under the Medicaid Drug Rebate Program[20] and reduced discounts under the 340B Drug Discount Program, which allows federally-designated providers to purchase discounted drugs.[21] Medicaid rebates and 340B discounts have two components: a base rebate/discount of 23.1 percent (for brand drugs) and an additional rebate/discount to offset price increases above inflation. These two rebates/discounts are calculated based on a drug's Average Manufacturer Price (AMP), which is an average of the prices of retail community pharmacy sales of the drug.[22] The CMS OACT estimates that AMP will fall by 3.2 percent under the proposal, reducing Medicaid rebates by $18.5 billion over ten years (no estimate is provided

[16] Pew Charitable Trusts. Medicare Part D Coverage Gap Proposal Would Not Reduce Drug Spending. Dec. 4, 2018. Available at: https://www.pewtrusts.org/en/research-and-analysis/articles/2018/12/04/medicare-part-d-coverage-gap-proposal-would-not-reduce-drug-spending.
[17] Public Law No. 115-123: Bipartisan Budget Act of 2018. February 9, 2018.
[18] CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.
[19] CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.
[20] Centers for Medicare & Medicaid Services. "Medicaid Drug Rebate Program." November 13, 2018. Available at: https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.
[21] U.S. Health Resources & Services Administration Office of Pharmacy Affairs. "340B Drug Pricing Program | Official web site of the U.S. Health Resources & Services Administration." https://www.hrsa.gov/opa/. Accessed February 25, 2019.
[22] 42 U.S.C. § 1396r–8(k).

for reduced 340B discounts).[23] CMS OACT estimates that lower drug prices under the proposal will offset most of this reduction, though this offsetting estimate assumes that manufacturers will voluntarily offer discounts to pharmacies for drugs dispensed to Medicaid patients.

Impact on Beneficiary Spending

Under the proposal, CMS OACT estimates that all Medicare Part D beneficiaries would see higher monthly premiums; premiums would increase by 19 percent in 2020, with a 25 percent total increase over the next ten years.[24] Over ten years, beneficiaries would spend an additional $58.0 billion in premiums.[25]

While all beneficiaries would see higher premiums under the proposal, only some beneficiaries would see lower pharmacy payments. Beneficiaries who take only generic drugs or very few drugs would be unlikely to see lower pharmacy costs, as these drugs generally do not have discounts that would move from rebates to lower pharmacy prices. However, beneficiaries taking expensive brand name drugs that currently have significant rebates would see much lower cost-sharing under the proposal.[26] Overall, the proposal would reduce beneficiary cost-sharing by $83.2 billion over ten years,[27] an 18 percent reduction in pharmacy payments.[28]

Some of the reduction in beneficiary cost-sharing may actually accrue to manufacturers, rather than beneficiaries. Medicare beneficiaries may be eligible to receive help paying their cost-sharing under Patient Assistance Programs (PAPs), which are charitable organizations that provide cost-sharing assistance.[29] Manufacturers generally fund PAPs, which are subject to a variety of requirements to avoid triggering liability under the AKS.[30] However, if beneficiary cost-sharing for high-priced drugs is reduced, any portion of that cost-sharing paid by the PAP will also fall, reducing the need for manufacturer contributions to the PAP. We are unaware of any reliable estimates of the amount of Medicare Part D cost-sharing currently covered by PAPs, but any estimated reduction in beneficiary cost-sharing that is currently paid by PAPs would accrue to PAPs and manufacturers, not beneficiaries.

Comparison to Other Drug Spending Proposals

Compared to other proposals to reduce drug spending, the current proposal significantly increases Medicare spending and manufacturer revenue while offering limited and uneven reduction in

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[23] CMS OACT. "Proposed Safe Harbor Regulation," p.6. August 30, 2018.
[24] 84 Fed. Reg. 2358.
[25] CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.
[26] 84 Fed. Reg. 2357.
[27] CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.
[28] 84 Fed Reg. 2358
[29] Centers for Medicare & Medicaid Services. "Pharmaceutical Manufacturer Patient Assistance Program Information." July 23, 2018. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html.
[30] Howard, David H. "Drug companies' patient-assistance programs—helping patients or profits?." *New England Journal of Medicine* 371.2 July 10, 2014. 371:97-99.

beneficiary costs. In 2018, Congress passed legislation increasing manufacturers' contributions to Medicare in the coverage gap from 50 percent to 70 percent.[31] Absent the proposal, this change would save Medicare $11.8 billion over ten years.[32] The proposal, however, effectively nullifies Congress' change in only one year, with Medicare estimated to spend an additional $13.4 billion in 2020 under the proposal.[33] Over the course of ten years, manufacturer coverage gap discounts would be $39.8 billion lower[34] – even after Congress increased the manufacturer coverage gap discount from 50 to 70 percent.

Recent legislation to increase generic competition, the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act), is estimated to reduce government expenditures by $3.3 billion over ten years and increase government revenues by $0.6 billion through increased fees.[35]

Similar to the proposal, a recent CMS proposed rule, CMS–4180-P Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,[36] would increase manufacturer revenues and increase Medicare spending.[37] This proposed rule would reduce beneficiary cost-sharing by applying a portion of pharmacy payments called Direct and Indirect Remuneration at the point of sale, similar to the proposal's application of current rebates at the pharmacy counter. This proposed rule would increase manufacturer revenues by $5.8 billion over ten years through reduced coverage gap discount payments; it would increase Medicare premium spending by $16.6 billion and beneficiary premium spending by $5.6 billion, offset by a $14.8 billion reduction in cost-sharing for some beneficiaries.[38]

Alternatives to Reduce Cost-Sharing

Other policies could reduce beneficiary cost-sharing without increasing manufacturer revenues. Under the Medicare Part D program, beneficiaries are generally required to cover 25% of total program costs through premiums and cost-sharing; the remainder is paid by taxpayers.[39] Congress could change this allocation, which would require plans to reduce beneficiary cost-sharing (though Medicare would make up the difference). Alternatively, CMS could establish a demonstration program that would allow plans to use a lower actuarial standard for cost-sharing, shifting more of costs to premiums.

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[31] Public Law No. 115-123: Bipartisan Budget Act of 2018. February 9, 2018.
[32] Congressional Budget Office. "CBO's Estimates of the Effects of Changes in the Manufacturers' Discount in the Part D Coverage Gap." July 20, 2018. Available at: https://www.cbo.gov/publication/54192.
[33] 84 Fed. Reg. 2360.
[34] CMS OACT. "Proposed Safe Harbor Regulation," p.5. August 30, 2018.
[35] Congressional Budget Office. "S. 974, Creating and Restoring Equal Access to Equivalent Samples Act of 2018." September 18, 2018. Available at: https://www.cbo.gov/publication/54479.
[36] 83 Federal Register 62152-62201, 62184. CMS–4180-P; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (RIN 0938-AT92). Nov. 30, 2018.
[37] Pew Charitable Trusts. "Pew Comments on Proposals to Modernize Medicare Drug Payments." January 25, 2019. Available at: https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2019/01/25/pew-comments-on-proposals-to-modernize-medicare-drug-payments.
[38] 83 Fed. Reg. 62192.
[39] Centers for Medicare & Medicaid Services. "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information." July 31, 2018. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2019.pdf.

To maintain competition through rebates and to maintain manufacturer contributions in the coverage gap, CMS could require plans to calculate beneficiary cost-sharing as a percentage of the net cost of a drug after rebates but accumulate beneficiary progression to the coverage gap based on the drug's up-front cost. This would shift some of the drug's cost from beneficiary pharmacy payments to premiums, but it would maintain manufacturers' contributions in the coverage gap. Shifting some costs to premiums may be desirable, however, as it reduces the cost burden on the sickest beneficiaries by spreading it evenly across all beneficiaries.

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We appreciate the opportunity to respond to this proposal and commend HHS for its attention to drug spending. Should you have any further questions, please contact us by phone at 202-540-6392 or via email at acoukell@pewtrusts.org.

Sincerely,

Allan Coukell, BscPharm
Senior Director, Health Programs

Sean Dickson, JD MPH
Officer, Drug Spending Research Initiative
The Pew Charitable Trusts